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FEB 2 0 2014

510(k) Summary

510(k) Number:	K131196
Date of Submission:	February 19, 2014
Submitter:	Fanem Ltda Rau Arthur Carl Schmidt, 186-CEP:07222-050 Cumbics Guarulhos SP Brazil Telephone: 55 11 6412-3743 Fax: 55 11 6412-2199
Official Contact:	Tara Conrad TechLink International Consulting 18851 NE 29th Avenue Suite 720 Aventura, FL 33180 Telephone: (305) 377-0077
Common Name:	Neonatal Phototherapy Unit
Trade Name:	Infant Phototherapy Bilitron Sky 5006
Classification:	Class II
Product Code:	LBI
Classification Panel:	General Hospital
Regulation Numbers:	21 CFR §880.5700
Substantial Equivalence:	NanoBlu 500 K113206

Indications for Use

The Fanem Infant Phototherapy Bilitron Sky 5006 is intended to treat neonatal hyperbilirubinemia by providing phototherapeutic light to the body of the patient. It is intended for use on the recommendation and under the supervision of healthcare professionals.

Device Description

The Fanem Infant Phototherapy Bilitron Sky 5006 is intended for the treatment of neonatal hyperbilirubinemia, commonly known as neonatal jaundice, in a hospital. They system can be used for infants in bassinets, incubators, open beds or radiant warmers. The lamp unit emits blue light, which falls within the phototherapy therapeutic spectrum. The Infant Phototherapy Bilitron Sky 5006 consists of a lamp unit and can be hood mounted or trolley mounted.

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Device Comparison Table

Features	Subject Device	Predicate Device
	Infant Phototherapy Bilitron Sky 5006 by Fanem K131196	NanoBlu 500 by Drager K113206
Intended Use	For the treatment of neonatal hyperbilirubinemia	For the treatment of neonatal hyperbilirubinemia
Target Population	Neonates	Neonates
Type	Freestanding device	Freestanding device
Mounting Hardware	Roll stand, 3 legs w/casters	Roll stand, 3 legs w/casters, 3 locking
Light Attachment	Lights mounted in enclosure	Lights mounted in enclosure
Light Source	Light Emitting Diodes (LED)	Light Emitting Diodes (LED)
Wavelength	400-550 nm	400-550 nm
Operating Voltage	100-240V	90 VAC to 240 VAC
Standards	IEC 60601-1 IEC 60601-1-2:2001 IEC 60601-2-50	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-50

Substantial Equivalence

The Infant Phototherapy Bilitron Sky 5006 and the NanoBlu 500 have the same intended use (treatment of hyperbilirubinemia), the same operating principle (delivery of blue light to degrade bilirubin), and are similar in their hardware configuration.

Non-Clinical Testing

This submission includes testing results of the Infant Phototherapy Bilitron Sky 5006.

Conclusion

Based on the data and information presented in this submission, the Infant Phototherapy Bilitron Sky 5006 is substantially equivalent to the currently legally marketed NanoBlu 500.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 20, 2014

Fanem Ltda
C/O Ms. Tara Conrad
TechLink International Consulting
18851 NE 29TH Avenue, Suite 720
Aventura, FL 33180

Re: K131196
Trade/Device Name: Infant Phototherapy Bilitron Sky 5006
Regulation Number: 21 CFR 880.5700
Regulation Name: Neonatal Phototherapy Unit
Regulatory Class: II
Product Code: LBI
Dated: October 29, 2013
Received: January 22, 2014

Dear Ms. Conrad:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer for

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K131196

Device Name

Infant Phototherapy Bilitron Sky 5006

Indications for Use *(Describe)*

The Fanem Infant Phototherapy Bilitron Sky 5006 is intended to treat neonatal hyperbilirubinemia by providing phototherapeutic light to the body of the patient. It is intended for use in the recommendation and under the supervision of healthcare professionals.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Digitally signed by Richard C. Chapman
Date: 2014.02.20 12:35:48 -05'00'

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